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10.(Amended) A process for increasing [igG] immunoglobulin concentration in a companion animal comprising the step of feeding said animal a diet containing [an effective amount] from about 1 to about 5 mg/day of lutein for a time sufficient for said lutein to be absorbed into the bloodstream of said animal.

11.(Amended) A process for increasing lymphocyte cells in a companion animal comprising the step of feeding said animal a diet containing [an effective amount] from about 1 to about 5 mg/day of lutein for a time sufficient for said lutein to be absorbed into the bloodstream of said animal.

Please cancel claims 13 and 15.

#### REMARKS

In the first Office Action, the Examiner initially rejected claim 8 under 35 U.S.C. §112, first paragraph, as containing subject matter which is not enabled by the specification. Specifically, the Examiner asserts that the specification does not describe what the limitation “crude” protein encompasses. However, applicants submit that the term “crude protein” is well known in the art which is expressed as 6.25 times nitrogen content, where 6.25 is a factor that relates the nitrogen content to the protein content of a food. Crude protein may be determined using the AOAC 990.03 method (Association of Official Analytical Chemists, Official Methods of Analysis, Arlington, VA 1994). Accordingly, claim 8 is believed to be in compliance with §112.

Claims 1-3 and 8-12 have been rejected under 35 U.S.C. §112, first paragraph, because the Examiner believes the specification to be enabling only for cats and dogs. However, the Examiner has provided no reasoning or evidence as to why the claims are not adequately enabled

by the disclosure. As the term "companion animals" is disclosed in the specification in terms which correspond in scope to the language in the claims, the claims must be considered to be in compliance with the enablement requirement §112 in the absence of any evidence or reasoning which suggests otherwise. See *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971).

Claim 10 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, it was suggested that clarification of the initials IgG be provided. Accordingly, claim 10 has been amended to recite immunoglobulin concentration.

Claims 13 and 15 have been objected to under 37 CFR 1.75(c) as being of improper dependent form. Claims 13 and 15 have now been cancelled.

Claims 1-5, 9 and 11 have been rejected under 35 U.S.C. §102(a) as being anticipated by Cerveny et al., Lutein Uptake by Blood and Leukocytes in the dog, AN 1998:203354 or Kim et al., Modulation of cell mediated immunity by dietary lutein in dogs, AN 1998:203976. In addition, claims 6-8, 10 and 12-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kim et al. or Cerveny et al. Applicant initially wishes to point out he is a co-author of these abstracts. Accompanying this paper is a Declaration pursuant to 37 CFR §1.132 by Michael G. Hayek, the named inventor in this application. Dr. Hayek states that the research reported in the published FASEB abstracts are publications of his own invention. Applicant notes that this patent application is entitled to the benefit of the April 16, 1998, filing date of provisional patent application Serial No. 60/081,968 which is specifically referenced at page 1 of this patent application. The Cerveny et al. and Kim et al. abstracts bear dates of publication which are less than one year prior to applicant's effective filing date. Accordingly, the declaration submitted herewith is, pursuant to MPEP §715.01(c) and *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982), sufficient to remove the Cerveny et al. and Kim et al. abstracts under 35 U.S.C. §102(a). Accordingly, the rejections must fail as Cerveny et al. and Kim et al. no longer constitute prior art.

Claims 1-11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Jyonouchi et al., Immunomodulating actions of carotenoid AN 1994:321921 in view of Anon, Ailment Specific dietary supplements, AN 97:19144. The Examiner asserts that it would have been obvious to one skilled in the art “to use the immunomodulation actions of lutein as demonstrated by Jyonouchi et al. and the supplemental forms of Anon in the administration of lutein for companion animals.” However, neither Jyonouchi et al. nor Anon teach or suggest the administration of a lutein supplement to companion animals such as dogs or cats. Jyonouchi et al. relate to a study conducted on mice. Further, neither Jyonouchi et al. nor Anon teach or suggest a dosage for companion animals as recited in amended independent claims 1, 9, 10 and 11. Accordingly, even if one skilled in the art were to combine the teachings of the two references, the claimed invention would not result.

Claims 12-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Biobusiness abstract 97:19144 (Anon). The Examiner has cited Anon for teaching that compositions comprising lutein are known in the art and asserts that it would have been obvious to use a lutein supplement for companion animals in the claimed amount. However, as previously pointed out, there is no teaching or suggestion in Anon of the use of a lutein supplement for companion animals such as cats or dogs. Anon appears to be directed to dietary supplements for humans. As pointed out in the background portion of the specification, few studies have been conducted on the physiologic function of lutein. Accordingly, Anon’s teaching of lutein-containing dietary supplements for humans does not suggest that there would be any expectation of enhancing the immune response in companion animals such as dogs or cats by the administration of lutein. Further, there is clearly no teaching in Anon which would lead one skilled in the art to administer a lutein supplement to companion animals in the claimed amounts.

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For all of the above reasons, applicant submits that claims 1-12, 14 and 16 as amended are in condition for allowance. Early notification of allowable subject matter is respectfully solicited.

Respectfully submitted,

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